

***United States Court of Appeals
for the Second Circuit***



**APPELLANT'S
BRIEF**

74-1738

To be argued by
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In The
United States Court of Appeals
For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION,
and SOLGAR, CO., INC.,

Plaintiffs-Appellants.

vs.

CASPER W. WEINBERGER, Secretary of Health Education
and Welfare and ALEXANDER M. SCHMIDT, Commissioner
of Food and Drugs,

Defendants-Appellees.

*On Appeal from the United States District Court
for the Southern District of New York.*

BRIEF FOR PLAINTIFFS-APPELLANTS

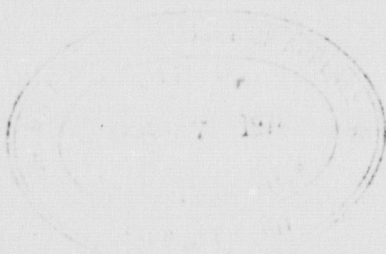
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UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 74-1738

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THE NATIONAL NUTRITIONAL FOODS
ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants

-v.-

CASPAR W. WEINBERGER, Secretary of Health,
Education and Welfare, and ALEXANDER M.
SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

_____o_____

BRIEF OF PLAINTIFFS-APPELLANTS

Introduction

Plaintiffs-appellants appeal to this Court from
an order of the United States District Court for the Southern
District of New York filed on April 6, 1974. The instant appeal
presents for decision important factual and legal questions
arising under the Federal Food, Drug, and Cosmetic Act 21 U.S.C.

section 301 et seq and the Administrative Procedure Act, 5 U.S.C. section 500 et seq. At issue is the unprecedented imposition of prescription requirements for certain vitamin A and D products which have previously been sold as dietary supplements. Appellants respectfully submit that the District Court erred in granting Appellees' motion for summary judgment in that the agency action at issue herein is both legally and factually invalid, and because summary judgment was in any event inappropriate and unwarranted in the instant case.

Statement of Issues Presented

1. Whether the Statement of Policy imposing prescription requirements for vitamins A and D is invalid as a matter of law under §503(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §353(b)(1)(B)].
2. Whether interpretive and substantive agency action are subject to differing standards of judicial review in terms of the right to a trial and the determination of a motion for summary judgment.
3. Whether Congress, under the Federal Food, Drug, and Cosmetic Act, has granted Appellees the authority to promulgate substantive prescription regulations, the violation of which is a civil or criminal offense.
4. Whether the District Court improperly granted Appellees' motion for summary judgment because the record filed

by the agency does not contain substantial evidence to support the agency action.

5. Whether the District Court improperly granted Appellees' motion for summary judgment because the "whole record" was not presented to the Court for decision and because the instant agency action was arbitrary and capricious.

6. Whether the District Court improperly vacated Appellants' notice to take the deposition of Appellees.

7. Whether vitamin A and D products can be classified as "drugs" within the statutory definition in §201(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §321(g)] merely because they contain quantities of said vitamins in excess of that considered by the Food and Drug Administration to be necessary in human nutrition.

Statement of the Case

A. Factual Background

Vitamins A and D, along with other dietary supplements, have been sold ever since 1938 as Foods for Special Dietary Use under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. The statute provides at 21 U.S.C. §343(j) that a food for special dietary use must bear on its label, "such information

concerning its vitamin, mineral and other dietary properties as the Secretary determines to be, and by regulations prescribes as necessary in order to fully inform purchasers as to its value for such uses." The procedure for the issuance of such regulations is governed by 21 U.S.C. §371(e) which included upon proper request by interested parties an opportunity for a full hearing before the agency.

Shortly after the enactment of the statute, such regulations were indeed promulgated and established at 21 CFR §125. By these regulations governing foods for special dietary use, manufacturers were required to list on their labels all of the dietary properties of the product in terms of informing the consumer as to the percentage of the Minimum Daily Requirement supplied by the product. Vitamins A and D, separately and in combination with other nutrients and foods have been marketed in accordance with these regulations for over 30 years. The instant action can only be fully understood in terms of a long attempted effort by the Food and Drug Administration to drastically alter the marketing status of all vitamin products. Beginning with a notice of proposed rule-making published in the Federal Register at 27 F.R. 5815, 1962, the Food and Drug Administration initiated administrative proceedings with a view towards revising the aforementioned regulations which had long

governed the labeling of foods for special dietary uses. In June of 1966, orders were promulgated by said agency seeking to establish restrictive standards of identity for dietary supplements and for the revision of labeling requirements for such products. 37 F.R. 8521 et seq., 1966. In accordance with statutory requirements, public hearings on these proposals commenced on June 20, 1968 and concluded nearly two years later on May 14, 1970. The transcript of these hearings which dealt with a whole range of issues involving vitamin products, comprises over 32,000 pages of testimony. Review of final regulations promulgated on the basis of these hearings is currently pending before this Court in a separate proceeding (NNFA and Solgar Co., Inc. v. FDA - Docket No. 73-2129, et al.).

In the course of the aforementioned public hearings, the Food and Drug Administration sought, in part, to justify a maximum limit in dietary supplements of 5,000 I.U. for vitamin A and 400 I.U. for vitamin D on the grounds that high dosages of these vitamins could be toxic. Various FDA and other witnesses dealt with this question and, as a result of vigorous cross-examination by opponents of the regulations, it was shown that the question of any possible toxicity of these vitamins related to the ingestion of astronomical quantities over prolonged periods of time which bore no relationship to the restrictive levels sought to be imposed in dietary supplements. (JA 29a-31a, 72a-83a, 172a) */

*/ All "JA" references are to the Joint Appendix.

On December 14, 1972, the Food and Drug Administration published a notice entitled "Vitamin A and D: Proposed Statement of Policy," (37 F.R. 26618) (JA 35a). The proposal outlined a prescription requirement for preparations containing vitamin A and D at potencies exceeding 10,000 I.U. and 400 I.U. respectively, by reason of the fact that "high dosages of such vitamins were known to be toxic." The proposal made no reference to the testimony adduced on this question at the aforementioned public hearings.

The only purported factual support for this proposal was a reference to a list of articles in the literature regarding these vitamins and their purported toxicity. (37 F.R. 26618 Col. 1) (JA 35a). Although the proposal stated that the Food and Nutrition Board of NAS/NRC was the recognized authority in the United States for determining human vitamin requirements (37 F.R. 26619 Col. 1) (JA 36a), no reference was made to findings of that Board with respect to toxicity of vitamins A and D. No analysis of the literature was referred to by the agency and available leading texts in the field were not cited. Sixty days were allowed for the submission of comments by interested persons.

The proposed Statement of Policy evoked massive opposition from both industry and consumers. (JA 32a).

Industry spokesmen, including Appellants herein, submitted detailed factual analyses of the literature cited by the Commissioner. (See e.g., JA 38a, 104a-179a). Additional material was presented reporting the analysis of the Food and Nutrition Board of NAS/NRC, as well as that found in leading texts in the field. Also noted in the comments was the failure of agency proposal to distinguish between children and adults in terms of possible adverse results from ingestion of vitamins A and D. (JA 40a, 172a). Every analysis of the literature submitted to the agency concluded that the prescription levels in the Proposed Statement of Policy were not supported by the available evidence and literature. No analysis of the literature was submitted in support of the agency position. Support of the agency action was limited to letters which simply endorsed the proposed action.

Despite the above opposition, the agency published its Statement of General Policy or Interpretation on the Status of Vitamin A and D, imposing the prescription requirements for all products labeled after October 1, 1973. (38 F.R. 20723, August 2, 1973) (JA 32a-34a, Add. A1). Plaintiffs commenced this action on August 6, 1973 seeking declaratory and injunctive relief to bar the enforcement of the aforementioned Statement of Policy. Plaintiffs' motion for preliminary

injunction was denied on September 25, 1973. NNFA and Solgar Co., Inc. vs. Weinberger, 366 F.Supp. 1341 (SDNY 1973). This Court affirmed the denial of such motion on December 11, 1973, holding only that the District Court had not abused its discretion in refusing to grant a preliminary injunction. On the prior appeal, this Court did not reach any of the legal or factual issues raised herein. See NNFA and Solgar Co., Inc. v. Weinberger, 491 F.2d 845 (2d Cir. 1973) (JA 347a).

In the District Court proceedings, Appellants submitted numerous affidavits and exhibits to the effect that the Statement of Policy with respect to vitamins A and D is factually and scientifically unreasonable and unsupportable. In response, Appellees filed with the District Court three cartons containing comments which had been submitted to the agency in response to the Proposed Statement of Policy and extracted therefrom and called to the Court's attention five letters which the agency received in support of the prescription requirement. (JA 192a-198a)*

Appellants thereafter served a notice to take the deposition of the Appellees or their knowledgeable designees with

*/ In addition, Appellees submitted to the Court copies of the articles listed in the bibliography which had been referred to in the original proposed Statement of Policy. (JA 35a) No specific citations or references to any of these articles was made by either party in the District Court proceedings (continued on page 9)

respect to the factual basis for the agency Statement of Policy. (JA 350a). Appellees responded by moving to vacate said notice of deposition and also requested that a prior motion by them to dismiss the complaint for failure to state a claim upon which relief could be granted should be treated as a motion for summary judgment. (JA 351a) The District Court vacated the aforesaid notice to take deposition and granted Appellees' motion for summary judgment. (JA 370a).

B. The Controversy Concerning Vitamins A and D

The dispute concerning vitamins A and D must also be viewed in terms of the general context of the controversy as to the role of vitamins in human nutrition. For many years leading experts on nutrition have differed widely as to the proper extent of and need for vitamin supplementation. (JA29a,35a,94a) It can fairly be said that the position of the Food and Drug Administration has been and continues to be hostile to those who have suggested that there are indications that greater amounts of vitamins are required for daily optimum nutrition and health.

*/ (cont'd from page 8)

and indeed neither of the two decisions in the District Court made any mention of such articles. At the specific request of counsel for appellees, however, all of these cited articles have been reproduced and presented to this Court. (See JA

367a and Exhibit Volumes I and II.

The Food and Drug Administration has sought to establish as definitive certain recommendations of the Food Nutrition Board of NAS/NRC with respect to daily vitamin intakes. With respect to vitamin A, for example, Recommended Daily Allowances (RDA's) are 5,000 I.U. for adults with lesser amounts recommended for various non-adult categories. (JA 36a) On the other hand, many leading nutritionists, including, for example, Nobel Prize winner, Dr. Linus Pauling, contend that there is evidence suggesting that the optimum daily intake of vitamin A for adults is properly set at 25,000 I.U. (JA 184a) The philosophy behind the general vitamin regulations, review of which is currently pending before this Court, Docket No. 73-2129, et al., is that vitamin products should be restricted to quantities which comport with the conservative nutritional views backed by the FDA.

The instant prescription limitations directly interfere with the marketing and consumption of such products which have been sold and used safely by millions of consumers for many years in accordance with the more liberal views as to optimal needs. For example, in order for a consumer to take 25,000 I.U. of vitamin A he would have to either pay a physician for a prescription or else take three tablets instead of one (two 10,000

I.U. tablets and one 5,000 I.U. tablet). Since the major item of cost in producing these products is found in the expense of the capsule itself as opposed to the vitamin content (JA 188a, 190a), the new limitations multiply the cost to manufacturers and thereby to consumers approximately threefold.

The nature of Appellants' objection to the instant agency action is therefore on two grounds. First, Appellants' position has been that vitamin A and D products in potencies very substantially in excess to those set as maximums by the instant agency action can be and have been safely used, particularly by adults, without adverse effects. Neither in the original agency proposal nor in the comments which accompany the final agency action has there been any express finding or contention that products then on the market resulted in adverse effects when taken in accordance with the recommended dosages on the label.

Secondly, it is Appellants' contention that the general and undocumented assertion by the agency that overzealous use and abuse of vitamin A and D products can lead to adverse effects by reason of ingestion of astronomical amounts over long periods of time, should not and cannot legally be

used to impose prescription requirements on quantities which can be and are appropriately labeled for safe use.

ARGUMENT

POINT I

THE STATEMENT OF POLICY IMPOSING PRESCRIPTION REQUIREMENTS FOR VITAMINS A AND D IS INVALID AS A MATTER OF LAW UNDER §503(b)(1)(B) OF THE FEDERAL, FOOD, DRUG AND COSMETIC ACT [21 U.S.C. §353(b)(1)(B)]

Section 503(b)(1)(B) of the Federal, Food, Drug and Cosmetic Act * sets forth specific and detailed requirements as to which products require a prescription under the statute. Whatever the scope of review for such agency action, it is clear that if such action is contrary to the statutory standards then the Statement of Policy must be found invalid as a matter of law. For the reasons set forth below, Appellants respectfully submit that there is no authority under the applicable statute for the imposition of a prescription requirement as attempted herein. The instant agency prescription requirement is not covered or contemplated by the prescription statute and is therefore in excess and beyond the statutory jurisdiction of the Food and Drug Administration.

The prescription statute establishes the following standard:

"(b)(1) A drug intended for use by man
which--

*/ In addition to portions of the statute quoted herein, relevant statutory provisions are set forth in full in the Addendum (Add.) hereto.

- (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;...

* * *

shall be dispensed only (1) upon a written prescription of a practitioner licensed by law to administer such drug,..."
§503 (b)(1)(B) [21 U.S.C. §353(b)(1)(B)]

There are, therefore, two requirements for the application of the prescription statute. First, a drug must be toxic or have other potentiality for harmful effect. The statute further requires, that because of such toxicity or potentiality for harmful effect the product be "not safe for use except under the supervision of a practitioner licensed by law to administer such drug."

The relationship between these two requirements can be illustrated by using aspirin as an example. Aspirin is not regulated by means of the prescription statute. In fact, the legislative history of the Act makes it clear that the Act was not intended to cover such a product. (See 97 Cong. Rec., p. 9323, Col. 2, p. 9348, Col. 2) (JA 244a). See also discussion of legislative history in United States v. Decholin, 264 F.Supp. 473 at 478-479 (E.D.Mich., 1967). The standard aspirin label states that adults should take one or two tablets every four hours and has a caution or warning against taking more than 12 tablets a day.

There is a further direction to contact a physician immediately in the event of an accidental overdose. The typical package insert varies the recommended dosages by noting that for children the dosage should be between one-quarter to three-quarters of a tablet, depending on the age of the child.

It is universally acknowledged that aspirin in excessive dosages is toxic, has a potentiality of harmful effect and can even result in death. As the standard labeling suggests, infants and children are more susceptible to such adverse results. Aspirin, however, does not meet either of the two requirements of the prescription statute. When used in accordance with the recommended dosages, aspirin is not toxic and does not have potentiality for harmful effect. Moreover, with respect to the second requirement, aspirin cannot be said to be unsafe for use except under the supervision of a practitioner. It can be used safely without such supervision in accordance with proper cautions, as noted above, and proper distinctions between children and adults. Consequently, aspirin cannot be classified as a prescription drug.

In the instant case, there has been no finding or assertion that vitamins A and D in excess of 10,000 or 400 I.U. respectively, are toxic. The District Court found, however, that these products have a "potentiality for harmful effect" because even a safe product could be abused and therefore lead to adverse results. (JA 343a). Completely overlooked by the District Court is the

legislative history and intent relative to the proper interpretation of the two statutory requirements as discussed above. In U.S. v. An Article of Drug Labeled Decholin, 264 F.Supp. 473 (E.D. Mich., 1967) (hereafter Decholin), the Court set forth at great length the various elements which must be considered before a prescription classification can be justified. Based on the legislative history of §503(b), the Court noted that the Act speaks of a drug "which is dangerous unless its use is superintended, and not of one which may cause harm if its administration is irrational, careless or imprudent." 264 F.Supp at 280. Thus, it is clear that Congress did not intend that a drug product be put on a prescription only basis, solely because some person may use it in an irrational, careless or imprudent manner.

"If in attempting to evaluate a drug, a court were to consider every contingency and take account of the immaturity or stupidity of every potential user, it would not be paying heed to the Committee's desire that it give to the word 'safe' the ordinary meaning." Id.

Clearly then, the Commissioner's statement in the proposal of December 14, 1972 that there are persons who may misuse available dietary supplements of vitamins and minerals (37 F.R. 26618) (JA 35a) is legally insufficient to automatically convert 10,001 I.U. of vitamin A or 401 I.U. of vitamin D to a prescription drug. As noted by the Court in Decholin, no prescriptions could be required for any product which will not cause harm when used in a reasonable manner:

"[I]t seems evident that the Committee thought that it was recommending passage of a bill which would take a drug out of unrestricted distribution only if it is hazardous for the reason that there is more than a remote possibility that it will cause harm when used in a reasonable manner." 264 F.Supp. at 480 (emphasis added)

At various points throughout its decision, the Court in Decholin quoted from and agreed with the legislative intent that no prescription be required for "common household remedies" such as aspirin, Bromo-Seltzer and milk of magnesia. (See e.g., 264 F.Supp. at 478-479). As observed by the Court, a proper interpretation of the statute does not support a "when in doubt, call it a prescription drug" principle. (264 F.Supp. at 480).

As noted in Decholin, supra, Congress, in enacting the prescription statute, was greatly concerned with preserving the availability of products without a prescription requirement. Congress has therefore laid down two types of regulation for drug products. One type is regulated under the prescription statute when they meet the statutory requirements discussed above. The second type of products are regulated by the statutory requirement that all drug products bear on their label adequate directions for use. (See §502(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §352(f)] (Add. A3). Thus, if a product can safely be used with adequate directions for use as contemplated by the statute, the prescription statute does not and was never intended to apply. This is, of course, inherent in the second requirement that the product be "not safe for use except under the supervision of a

practitioner."

In the instant case, the Commissioner expressly recognized that proper cautionary labeling can be sufficient to protect the public. In the comments accompanying the final agency action with respect to the Statement of Policy, the Commissioner notes:

"Comment was received that consumers would be able to ingest as many dosage units as they desired and therefore the proposed limits would have no effect. The Commissioner cannot agree with this concept. Today's consumers are increasingly knowledgeable and are concerned about the health and safety of themselves and their family. The Commissioner believes that most consumers will carefully consider the advisability of taking dosage units in excess of suitable recommended daily dosages." (38 F.R. 20724, Col. 3) (JA 33a).

The finding of the lower court herein was that the purpose of the instant agency action was to set up "an obstacle to the swallowing of toxic amounts." (JA 346a). At no point has either the agency or the lower court attempted to define, on the basis of the available evidence, the range where ingestion of vitamins A and D could lead to adverse results. It is, therefore, clear that the agency is seeking to place safe quantities of vitamins A and D on a prescription basis not because such quantities are intrinsically dangerous but only because abuse of such products might lead to ingestion of unspecified "high dosages" (JA 34a, 36a, 361a) irrespective of proper cautionary labeling on such products. As a matter of law, this approach by the agency has no basis under the prescription statute. The statute requires a finding that the product be "not safe for use except under the

supervision of a practitioner." Under Appellee's rationale, as accepted by the District Court, almost all over-the-counter drugs could be placed on prescription basis because if abused they might have harmful effects. Manifestly, this is not what Congress intended. */

It should be noted that both the original agency proposal in this matter and the final agency action make absolutely no reference to the specific statutory requirements of the prescription statute as discussed above. Inevitably, the rationale of the agency is intertwined with its nonstatutory philosophy of proper nutrition which has no relationship to the prescription statute. Since the prescription limitations on vitamins A and D are not designed to meet the requirements of or to achieve the purpose of the prescription statute, the lower court improperly granted Appellees' motion for summary judgment and the instant agency action is therefore invalid as a matter of law.

*/ A recent decision in American Pharmaceutical Association v. Weinberger, Civil Action No. 1485-73 (D.D.C., June 5, 1974) rejected a very similar attempt by the Food and Drug Administration to go beyond the statute with respect to "safe" use of drugs. The court noted with respect to the new drug provisions of the Act:

"Defendants argue that the term 'safe' should be interpreted with reference not only to the inherent qualities of the drug under consideration but also in the sense of the drug being secure from possible misuse...[B]y examining the term 'safe' in the context of those provisions of the Act in which it appears...the court concludes that the term 'safe' was intended to refer to a determination of the inherent safety or lack thereof of the drug under

(continued on p. 19)

POINT II
INTERPRETIVE AND SUBSTANTIVE AGENCY ACTION ARE
SUBJECT TO DIFFERING STANDARDS OF REVIEW IN
TERMS OF THE RIGHT TO A TRIAL AND THE DETERMINA-
TION OF A MOTION FOR SUMMARY JUDGMENT

In granting Appellees' motion for summary judgment, the lower court held that Appellants were not entitled to a trial and could not take the deposition of Appellees in order to ascertain the basis for the instant Statement of Policy. The court thereupon found that in its view the regulations were not arbitrary or capricious and that a wider evidentiary review was not appropriate. In this connection, the District Court found it "unprofitable" to explore the distinctions as to scope of review as between interpretive and substantive agency action. (JA 3^e a).

Appellants respectfully submit that the approach taken by the District Court was totally inadequate for a proper resolution of the issues presented by the motion for summary judgment. Such a resolution required a determination of the proper scope of review and its application to the facts of the instant case. The proper scope of review, in turn, cannot be determined until the nature of the agency action is established. Substantive and interpretive regulatory action involve different

*/ (continued from p. 18)

consideration when used for its intended purpose."
(Add. A23-24)

As a result, the court held that the agency interpretation as to the proper channels for distribution of the drug product involved was invalid. The entire, as yet unpublished, opinion is set forth in the Addendum at Add. A18

concepts and standards of review and their application to the instant case clearly shows that there was no basis in either law or fact for the granting of Appellees' motion for summary judgment.

Appellants respectfully submit that the instant agency action was, as its name clearly implies, an interpretive Statement of Policy with respect to which Appellants, at the very least, were entitled to a trial as to the triable issues of fact which were raised below. In both the proposed Statement of Policy, as well as the final version, the accompanying comments stressed that it was the "opinion" of the agency that these levels were appropriate. (JA 33a, 36a).

The failure of the District Court to inquire and determine the status of the instant agency action as an interpretive or substantive rule-making function was therefore a fundamental error in terms of deciding the motion for summary judgment. Substantive rule-making involves a statutory grant of authority to an agency to make policy or factual determinations which are ultimately to have the force and effect of law.

Interpretive rule-making, on the other hand, deals with legal interpretations of a statute or Statements of Policy as to the application of statutory standards to concrete factual situations. Interpretive rules and statements of policy are by definition not binding upon the courts and the parties adversely affected can challenge such regulations in enforcement proceedings. The above distinctions between interpretive and substantive agency action have long been recognized by Congress and the Courts.

The Administrative Procedure Act makes a very sharp distinction between substantive agency action and interpretive general statements of policy. Although both items are included within the Act's definition of "Rule Making" [see 5 U.S.C. §551(4)-(5)], the distinction is found in 5 U.S.C. §553 where the requirements for public participation are set forth for substantive regulations. Thus, at 5 U.S.C. §553(b), the statute states:

"Except when notice or hearing is required by statute, this subsection does not apply --

(A) to interpretive rules, general statements of policy or rules of agency organization, procedure or practice...."
(emphasis added)

The only requirement for general statements of policy, such as the one promulgated with respect to vitamins A and D, is

that they be published in the Federal Register so that the public will be aware of the policy. 5 U.S.C. §552(a)(1)(D). Thus, interpretive rules and general statements of policy are exempt from the notice requirement which apply to substantive regulations. The explanation for this distinction is clearly set forth in the legislative history of the Administrative Procedure Act:

"The reason for the exclusion of rules of organization, procedure, interpretation and policy is threefold: First it is desired to encourage the making of such rules....Another reason which might be added, is that 'interpretive' rules - as merely interpretations of statutory provisions - are subject to plenary judicial review...." House Report No. 1980, 79th Congress 2d Session at p. 18.

Similarly, the distinction between interpretive and substantive regulations was explained in the report of the Attorney General in support of the Administrative Procedure Act:

"Administrative rule-making, in any event includes the formulation of both legally binding and interpretive regulations. The former receive statutory force upon going into effect. The latter do not receive statutory force and their validity is subject to challenge in any court proceeding in which their application may be in question. The statutes themselves and not the regulations remain in theory the sole criterion of what the law authorizes or compels and what it

forbids." Report of the Attorney General's
Committee on Administrative Procedure (1941)
(emphasis added)

Similarly, the above distinction has been recognized in a long
line of judicial decisions. In Skidmore v. Swift & Co., 323 U.S.
134 (1944), the Supreme Court of the United States clearly
explained this distinction as follows:

"We consider that the rulings, interpretations
and opinions of the Administrator under this
Act, while not controlling upon the courts by
reason of their authority, do constitute a body
of experience and informed judgment to which
courts and litigants may properly resort for
guidance. The weight of such a judgment in a
particular case will depend upon the thorough-
ness evident in its consideration, the validity
of its reasoning, its consistency with earlier
and later pronouncements, and all those factors
which give it power to persuade, if lacking
power to control." Id. at 140 (emphasis added)

Many courts have recognized this basic distinction. See
Gibson Wine Co. v. Snyder, 194 F.2d 329 at 331-332 (D.C. Cir. 1951);
American President Lines, Ltd. v. Federal Maritime Commission, 316
F.2d 419 at 422 (D.C. Cir. 1963); O'Neill v. United States of
America, 281 F.Supp. 359 at 363 (D. Ohio 1968) aff'd 410 F.2d
888 (6th Cir. 1969); Matczak v. Secretary of HEW, 299 F.Supp.
409 at 412, nt. 4 (EDNY 1969); Continental Oil Co. v. Burns,
317 F.Supp. 194 at 200 (D. Del. 1970); Soriano v. United States,

494 F.2d 681 at 683 (9th Cir. 1974). See also Davis, Administrative Law Treatise (1958) §5.03-.05; 1970 supplement to Treatise §5.03-.04.

The distinction between interpretive and substantive regulations can be explained by comparing two types of regulations under the Federal Food, Drug, and Cosmetic Act. Under §401 [21 U.S.C. §341] and §701(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §371(e)] , the Commissioner of the Food and Drug Administration is given the authority to promulgate standards of identity for various food products. After such a standard is duly promulgated in accordance with the substantive statutory grant of authority, a food product which is sold in violation of the standard is subject to criminal and civil enforcement procedures under the Act. The standard, therefore, has the force and effect of law. All that the agency must prove in an enforcement proceeding is that the standard was violated.

Interpretive rules and statements of policy on the other hand do not by themselves have the force and effect of law. Their legal and factual validity is dependent on the application of the statute by the courts. For example, §402(a) (4) of the Act [21 U.S.C. §342(a)(4)] provides that a food is adulterated and, therefore, subject to criminal and civil proceedings if the food was prepared in a manner which was not in

accordance with "good manufacturing practice." The Food and Drug Administration issued an interpretive regulation with respect to the term "good manufacturing practice." In United States of America v. Everett Fisheries, Inc., 72 C.R. 109 (W.D.Wisc. May 30, 1973) */ the court held with respect to such interpretive regulation:

"[I]n each case the government must present its evidence so as to persuade the finder of fact and the defense must have its opportunity to dispute and that the judgement exercised by the Food and Drug Administration in promulgating regulation 128a, Subpart A is not to be given automatic and decisive effect in the case; rather, that the regulations in question are to be given just such effect as the trier of fact may consider that they deserve on the basis of the evidence in the case." (Add. A13) (emphasis added)

For many years it was thought that interpretive rulings and statements of policy were not subject to pre-enforcement judicial review because the requisite ripeness was lacking in connection with the "case or controversy" requirement of the United States Constitution." See e.g. Helco Products Co. v. McNutt, 137 F.2d 681 (D.C.Cir. 1943); Abbott Laboratories v. Celebrezze, 352 F.2d 286 (3rd Cir. 1966); American President Lines, Ltd. v. Federal Maritime Commission, supra.

*/ A copy of this unpublished opinion is reproduced at Add. A10.

The judicial view of pre-enforcement relief was changed drastically as a result of the landmark decision in Abbott Laboratories v. Gardner, 387 U.S. 136 (1967). The Supreme Court held that although interpretive agency action was not binding in the strict sense, it did present a justiciable controversy to the extent that it imposed on the affected members of the public the dilemma of either complying with the agency action or risking severe sanctions in enforcement proceedings. The Court, therefore, endorsed pre-enforcement relief as an expeditious method of determining the validity of interpretive agency action by way of a declaratory judgment suit. 28 U.S.C. §2201. */

Appellants respectfully submit that the scope of judicial action in a suit for pre-enforcement judicial relief should be the same as that in the ultimate enforcement proceeding

*/ In the brief opinion of this Court in Ciba-Geigy Corp. v. Richardson, 446 F.2d 446, 468 (2d Cir. 1971), the somewhat ambiguous statement is made that the Food and Drug Administration has the authority to issue "binding interpretive regulations" under the decision of Abbott Laboratories discussed in the text. It is respectfully submitted that the lower court's reference to this decision (JA 380a) is misplaced. The decision in Abbott Laboratories expressly noted that interpretive regulations become binding upon the parties involved only after judicial review is obtained. 387 U.S. 136 at 154 (1967). It is in this same context that the comment of this court in Ciba-Geigy must be understood.

which it seeks to anticipate. The District Court herein has suggested that in an enforcement proceeding, such as the criminal case in Everett Fisheries, supra, the scope of judicial action is different than in a suit for a declaratory injunction. (JA 389a). Such an approach would defeat the very purpose of pre-enforcement declaratory injunction suits which seek to obtain a judicial determination in lieu of the severe sanctions which could be imposed if the only alternative were to wait for agency enforcement proceedings. The decision of the Supreme Court in Abbott Laboratories, supra, should not be taken as a departure from the long-established principles governing interpretive rules and statements of policy. */ Abbott Laboratories expanded allowable review by approving pre-enforcement relief, but in no way altered the scope of judicial action upon such challenge to interpretive agency action.

The interpretive nature of the instant Statement of Policy was at first fully conceded by Appellees in the District Court:

*/ In the landmark decision of the Supreme Court of the United States in Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971), the Court was dealing with review of substantive agency action under the Administrative Procedure Act. That Court's discussion of limitations on the right to a trial has no reference to interpretive agency action.

"Indeed, the Commissioner actually provided a greater opportunity for public participation in the rule making process than was required. The present regulations appear in Title 21 of the Code of Federal Regulations, Part 3 - "Statements of General Policy of Interpretation." The Administrative Procedure Act, 5 U.S.C. §553(b), specifically provides that a notice of proposed rule making in the Federal Register is not required for "interpretative rules" or "general statements of policy," yet the Commissioner published a detailed notice of proposed rule making in the Federal Register inviting comments. " (Defendants' memorandum in opposition to motion for a preliminary injunction, p. 13) */

Appellants respectfully submit that the scope of review in the District Court is not altered merely because the agency gratuitously extended an opportunity for the submission of comments with respect to an interpretive Statement of Policy. Surely, if no comments had been requested, the interpretive Statement of Policy would have been subject to a full legal and factual challenge in the District Court. The comments which were gratuitously compiled by the agency cannot serve to create a legal "record" where none is required or contemplated by the statute. In the absence of any legal entity herein which can be described as a "record," Appellants were entitled to a full

*/ It was only after Appellees moved below for summary judgment that it was first contended that the agency action might be considered substantive.

trial in the District Court as to the factual issues raised by the attempted imposition of prescription requirements. */ By issuing an interpretive regulation, the agency cannot avoid the burdens of a factual inquiry such as the one which they clearly had to bear in the Decholin case. It is of course axiomatic that no motion for summary judgment can be granted where there are outstanding questions of fact to be resolved. In the instant case, it is obvious that many such unresolved factual questions were before the District Court.

Appellants submitted to the Court medical affidavits and other evidence to the effect that the prescription levels set for vitamins A and D are unsupportable in light of the medical knowledge as to the purported toxicity of these vitamins. See affidavits submitted in support of preliminary injunction

*/ See Salazar v. Hardin, 314 F.Supp. 1257 (D.Col. 1970) where the decision of the Court indicates that a trial was had with respect to an interpretive regulation. Id. at 1259.

The attention of the Court is also respectfully directed to a recent comment by Judge Friendly in NNFA and Solgar Co., Inc. v. FDA, 491 F.2d 1141 (2d Cir. 1973). In distinguishing between a §701(e) regulation involved in that case and a §701(a) regulation involved in Toilet Goods Assn. v. Gardner, 360 F.2d 677 (2d Cir. 1966), Judge Friendly described the latter as follows:

"The comment was made with respect to rules not protected by the usual provisions making findings supported by substantial evidence conclusive and limiting the production of new evidence. Both sides in the Toilet Goods case contemplated a trial if the government's motion to dismiss [for lack of jurisdiction] were not granted." Id. at 1143

and reply affidavit of Joseph John Vitale. (JA 8a-89a, 92a-95a).

Appellees below, while not submitting any medical affidavits, filed the aforementioned collection of comments with the Court and cited to the Court five letters from medical sources supporting the proposed Statement of Policy. At the very least, this presents questions of fact requiring a trial which necessarily precluded summary judgment for Appellees.

The decision of the District Court granting summary judgment, in effect, defers to the asserted expertise of the agency which in the instant case has simply proclaimed that in its opinion the levels chosen are justified. While deference to the expertise of an agency may properly play a role in the evaluation of the total factual background by a trier of fact, the invocation of such expertise cannot be used to frustrate legitimate factual inquiry and challenge to the agency's factual premise. The ruling of the District Court represents an abdication of judicial responsibility in that Appellees' motion for summary judgment should have been denied in that it was premature and unwarranted by the law and facts of the instant case.

POINT III

CONGRESS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DID NOT GRANT APPELLEES THE AUTHORITY TO PROMULGATE SUBSTANTIVE PRESCRIPTION REGULATIONS, THE VIOLATION OF WHICH IS A CIVIL OR CRIMINAL OFFENSE

A. The Legislative History Of The Prescription Statute Shows That Congress Expressly Sought To Preclude Substantive Authority With Respect To Prescription Status.

The Food and Drug Act is quite specific in its grants of authority for substantive legislative regulations. The prescription provisions in 21 U.S.C. §353(b)(1)(B) do not provide for any regulations, and there is no authority for issuing substantive regulations classifying products as prescription items. */ The specific legislative history of the prescription statute shows that Congress expressly refused to give the agency the power to issue substantive regulations with respect to classification of prescription drugs. At present the prescription statute provides:

"21 U.S.C. §353(b)

(1) A drug intended for use by man which --

* * *

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug;...shall be dispensed only (i) upon a written prescription..."

*/ It is interesting to note that with respect to habit forming drugs covered by 21 U.S.C. §353(b)(1)(A) there is statutory (continued on p. 32)

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed misbranded if at any time prior to its dispensing its label fails to bear the statement 'Caution: Federal Law prohibits dispensing without a prescription.'

By deeming such improperly labeled drugs misbranded, the statute allows for enforcement by seizure, injunction and criminal actions under enforcement provisions of the Act. [21 U.S.C. §331(c), §333 and §334].

Prior to the enactment of the above-quoted section, there was no provision or standard in the statute specifically governing prescription drugs. Instead, prescriptions were required if such was necessary as part of the more general requirement for adequate directions for use on all drug products, [21 U.S.C. §352(f)(1)]. In order to provide some guidance, the agency promulgated an interpretive regulation with requirements which were essentially the same as the ones later incorporated in the statute. See 21 CFR §2.106 (b)(1) and (b)(2)(ii) (1944 Supp.).

Various difficulties arose under the above system of determining prescription status which ultimately led to the enactment of the current prescription statute at 21 U.S.C. §353(b). These difficulties are outlined in House Report No. 700, 82nd Congress, 1st Session accompanying H.R. 3298.

Although there was broad agreement as to the need for change, there was strong disagreement as to how to accomplish it. Ultimately, this disagreement was resolved on

*/ (continued p. 31)
authority for the promulgation of a regulation which brings the prescription requirement into operation. See 21 USC §352(d).

the floor of the House of Representatives by the enactment of an amendment which eliminated a substantive grant of authority for prescription regulations. This involved the rejection of the decision of the House Committee which had considered the issue. The House Committee Report had noted:

"Determination of What Drugs Are Prescription Drugs

Conflicting Legislative Recommendations

The committee was confronted with a dilemma in that the trade and professional organizations representing the different interested groups have made conflicting recommendations. The National Association of Retail Druggists, on the one hand, has urged that in the interest of achieving the greatest possible certainty for the retail druggists and the general public, the Federal Security Administrator should be vested with the power to determine on the basis of a statutory standard, but subject to judicial review, which drugs are to be sold on prescription only. The drug manufacturers, on the other hand, represented by the American Pharmaceutical Manufacturers' Association, and the Proprietary Association, and those pharmacists who are represented by the American Pharmaceutical Association, have opposed the vesting of any such authority in a Federal official. They have contended that the determination of which drugs may be sold only on prescription, should be left to judicial determination on the basis of a statutory standard, in court proceedings (seizure, criminal prosecution, or injunction) instituted by the Federal enforcement officials.

The Committee's Decision

The committee has thoroughly studied the arguments adduced by both sides in favor of their respective proposals. It has come to the conclusion that administrative determination, subject to judicial review, gives the greatest promise of effectively relieving the retail druggists and the general public from the presently existing confusion." House Report pp. 8-9 (emphasis added (JA 253a)

The minority committee report, whose view was later adopted by the House and enacted into law, vigorously objected to the grant of substantive authority to the agency and noted:

"We believe that the enactment of the foregoing provisions of the bill (allowing oral prescriptions) is as far as Congress should go at this time in making changes in the present law.... The remaining provisions would make basic changes in the method of determining which drugs are dangerous and may be sold only on prescription and which drugs may be sold over the counter. We think the present method, which leaves this determination to the courts, should be left unchanged except that a proper standard to be applied in determining whether a drug is dangerous should be incorporated in the statute."
House Report, supra, p. 28 (JA 273a)

When the bill reached the floor of the House, there was vigorous debate as between these two opposing views. As reported by the majority of the House Committee (later rejected by the House), the bill would have established a standard for prescription requirements and would have allowed the agency to determine which drugs required a prescription under the standard. Any interested person could file objections to the agency determination whereupon a public hearing would have been held leading to an agency order determining the matter with judicial review in the Court of Appeals. See House Report, supra and 97 Congressional Record 9334 col. 1 and 2 (August 1, 1951). (JA 246a, 247a, 229a, 230a). Advocates of the position taken by the minority committee report insisted that there be no substantive grant of authority to the agency and that instead a

statutory standard be incorporated in the statute to be applied by the Courts in enforcement actions. It was this approach which was adopted by the House and which constitutes the present prescription statute. The following excerpts from the debate [97 Congressional Record 9235-9243 (July 31, 1951) and 9321-9349 (August 1, 1951)] indicate the nature of the arguments and their resolution. (All page references are to 97 Congressional Record): */

MR. ALLEN: "All opposition to this bill centers around the extraordinary powers proposed to be granted to Federal Security Administrator Oscar Ewing. If this bill is not amended, Oscar Ewing will have the power under this bill to determine what drugs will be sold; and, if they are permitted to be sold, whether or not they will be sold over the counter or upon prescriptions....In my opinion this is an unjustifiable delegation of power to an administrative agency." (p. 9237 col. 3) (JA 210a)

MR. MORANO: "Has the gentleman any idea as to whether an amendment will be offered to delete that section from the bill...?"

MR. ALLEN of Illinois: "I understand such an amendment will be offered...." (p. 9238 col. 2) (JA 211a)

MR. O'HARA: "May I say, Mr. Chairman, that I intend to offer an amendment which will strike out the objectionable features of this bill, namely, amending B and striking out subsection 5. That will remove this tremendous grant of administrative absolutism to Mr. Ewing as the Food and Drug Administrator, and I am sure a great many Members and many, many of the people of this country do not want him to have such power." (p. 9327 col 2) (JA 223a)

* * *

*/For the convenience of the Court the entire Congressional debate is included in the Joint Appendix and citations are also made thereto.

"My amendment will then strike out subsection (5), which is the grant of power to the Administrator....The burden of proof is reasonably upon the Administrator when he comes into court to enforce the authority which he has now. There is no question but that the Administrator has all the power in the world now. If a drug is mislabeled or misbranded or not approved as it should be for sale to the public, the Administrator has all the authority in the world to bring prosecution, either criminal prosecution, or to seize it under a libel, and prosecute that action." (p. 9328 col. 1) (JA 224a)

* * *

MR. KERSTEN: "Mr. Chairman, as I understand the present bill, without the amendment it would be incumbent upon the Administrator to decide what drugs could be prescribed and those that could not be prescribed; in other words, he would have the responsibility of that rather very important function. It is true that there are a certain number of difficulties and there may be uncertainties in the present system, but in my humble opinion we are not solving them by putting this power in the hands of an administrator....In my opinion, with all of its difficulties the present system is superior.... If a mistake is made by the Administrator the effects are Nation-wide."

* * *

"We might have a situation where the Administrator could say, 'We will approve your product,' and this approved product would be on the 'white list,' or the Administrator could say 'I will not approve your drug for sale except by prescription, therefore this product would be on the black list,' as far as the sale over the counter is concerned. I do not think that situation should exist. Unless the O'Hara amendment is adopted, such a situation could develop....The authority proposed might well be properly administered. On the other hand, it could be misabused or abused. I think existing authority is quite sufficient and that section (B) is not needed, and, therefore, that the O'Hara amendment should be adopted." (p. 9347 col. 2, 3 and p. 9348 col. 1) (JA 243a-244a)

MR. BENNETT: "Mr. Chairman, the effect of the O'Hara amendment is relatively simple. What it does is to legalize the regulations under

which the Food and Drug Administration has been operating in this field for a period of years. Section (B), as set forth in the O'Hara amendment, substantially embodies the terms of the present regulations. What is wrong with that, and why does the Food and Drug Administration want it changed? Simply this: Here is the procedure they are obligated to follow at present. If a drug manufacturer dispenses a prescription drug on a nonprescription basis, which Food and Drug feel is dangerous, they proceed against the manufacturer in several ways, either to prosecute him criminally, proceed against him by injunction, by enjoining him from further manufacture, or by confiscation, or by any combination of those remedies. Now what about the case of the druggist? Under this system if the retail druggist sells a drug in accordance with the label put on it by the manufacturer, if he acts in good faith, he is not subject to prosecution, even though the drug manufacturer would be. All they can do is to confiscate the drugs. If they confiscate his drugs, he has his recourse against the manufacturer. This is rational procedure.

But here is what the Administrator wants to do. He does not want to give the manufacturer or the druggist his day in Court. The burden of proof is on the manufacturer or druggist. They must go into court and show that the drug is actually safe without a prescription. The Administrator wants an easier way. It is more difficult to give a man his day in court with the presumption in his favor than to proceed by administrative regulation, which provides no presumption for the citizen.

But it is safer and wiser to pursue a different course. Let us stay on the safe side by adopting this amendment." (p. 9348 col. 2-3) (JA 244a)

THE CHAIRMAN: "The time of the gentleman from Ohio (Mr. Crosser) has expired.

All time has expired.

The question is on the amendment offered by the gentleman from Minnesota [Mr. O'Hara].

The question was taken; and on a division (demanded by Mr. Harris) there were - ayes 141, noes 85.

So the amendment was agreed to."

THE SPEAKER: "The question is on the passage of the bill. The bill was passed." (p. 9349 col. 3)(JA 245a)

The O'Hara Amendment, which is the present prescription statute, was thus designed to expressly deny the agency the power to substantively determine what products would require a prescription. Instead, the O'Hara Amendment incorporated into the statute the standard which had previously been contained in the agency's interpretive regulation with enforcement in the courts available to determine if the statutory standard had been violated.

After passage in the House, the bill was sent to the Senate where a bill similar to the original House bill was pending. The Senate Committee considering the bill accepted the final version of the House and recommended it for passage. There was no debate in the Senate and the bill was passed. The report of the Senate Committee notes:

"As previously stated, the committee considered S. 1186 together with H.R. 3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry. and the committee concluded that administrative listing is not necessary at this time. It was felt that the statutory definition, together with the authority to make interpretive regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan." Senate Report, No. 946 82nd Congress, 1st Session, pp. 4-5 (emphasis added) (JA 286a-287a)

The above discussion of the legislative history clearly shows that Congress expressly refused to grant the agency the power to make substantive regulations as to prescription requirements which would have the effect of denying litigants a full trial in a District Court. Instead, the Senate Committee suggested that the agency resort to interpretive regulations to obtain industry cooperation, with seizures and injunctions as the ultimate enforcement weapons. Appellees' claim of substantive authority is expressly refuted by the legislative history of the prescription statute. The Statement of Policy issued by the FDA can, therefore, not be a substantive (i.e., legislative) regulation since there is no authority in this statute for such an exercise of substantive authority and which would in fact be contrary to the congressional intent. The agency action challenged herein is clearly an interpretive statement of general policy which serves to inform the public as to how the agency intends to enforce the Act.

B. Section 701(a) Of The Federal Food,
Drug, and Cosmetic Act [21 U.S.C.
§371(a)] Does Not Authorize Substan-
tive Prescription Regulations.

Despite the clear showing from the legislative history of the Act that Congress never intended to give the agency substantive authority with respect to the prescription status of drug items, the District Court held that such regulations are authorized by the general grant of power in §701(a) of the Act. (JA 378a, 379a) Thus, although it is clear that Congress intended that the Food and Drug Administration have only "interpretive" authority with respect to prescription drugs, the lower

court ruled that because Congress had "not done anything to §701(a) of the Act," the congressional intent is frustrated because substantive authority exists in any event under §701(a). */

Once again, the District Court failed to determine the nature of the authority granted in §701(a) of the Act. The legislative history of §701(a) of the Act, as well as the structure of the Federal Food, Drug, and Cosmetic Act, show that this section was not intended to grant the agency substantive authority to promulgate the regulations which have the force and effect of law. Instead, §701(a) authorizes only interpretive regulations, the violation of which is not per se a civil or criminal offense and with respect to which Appellants are entitled to a full trial in the District Court.

Two types of regulations are contemplated by the Federal Food, Drug, and Cosmetic Act under the general rubric of §701. Section 701(e) [21 U.S.C. §371(e)] of the Act provides a detailed procedure for the issuance of specified regulations including detailed notice requirements, opportunity for the filing of objections, the holding of an evidentiary public hearing, and judicial review in a United States Court of Appeals. By way of contrast, §701(a) merely states the general proposition that the Secretary (whose authority has been delegated to the Commissioner of Food and Drugs) is authorized to promulgate regulations

*/ The lower court's opinion mistakenly notes that Appellants' position is that the regulations are not authorized at all. (JA 372a). Any agency can issue an interpretive ruling or statement of policy and no challenge has been made herein as to the agency's exercise of that power.

for the efficient enforcement of the Act. No procedure is specified for the issuance of such regulations and the statute contains no express explanation as to the types of regulations encompassed by §701(a).

The legislative history of the Act, however, makes it abundantly clear that in establishing the distinction between §701(a) and §701(e) regulations, Congress was referring to the traditional distinction between interpretive and substantive regulations. Thus, with respect to the §701(e) regulations the House Report accompanying the proposed Federal Food, Drug and Cosmetic Act takes pains to note:

"Such regulations are not merely interpretive, they have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of goods involved if shipped in interstate commerce or their exclusion from the country if imported." Report No. 2139, House of Representatives, 75th Congress, 3rd Session, pg. 4: Dunn, The Legislative History of the Federal Food, Drug, and Cosmetic Act, pg. 824.

It is therefore apparent, that in establishing the §701(e) procedure, Congress expressly sought to set up a system whereby regulations issued thereunder would have the force and effect of law as opposed to interpretive regulations, the issuance of which was not governed by the §701(e) procedure. Any doubt on this score, however, is resolved by an earlier comment in the House Report which in discussing the regulatory authority under the Act notes:

§701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given

and that adequate time shall be given after the promulgation of a regulation before it becomes effective." Report No. 2139, House of Representatives, 75th Congress, 3rd Session, p. 4: Dunn, The Legislative History of the Federal Food, Drug, and Cosmetic Act, p. 823.

The congressional intent was thus expressly indicated to the effect that any regulation which has the effect of imposing civil or criminal penalties has to be governed by the §701(e) procedure which includes the right to a public hearing. The §701(a) regulations necessarily relate therefore to interpretive regulations which the House Report clearly indicates are of a different nature.

Moreover, the general structure of the Federal Food, Drug, and Cosmetic Act clearly shows that the claimed authority for the issuance of substantive prescription regulations without an evidentiary hearing or an evidentiary scope of review is unjustified. The Act provides for various types of regulatory procedures with respect to determining factual questions as to the safety, effectiveness and wholesomeness of various food and drug products. For example, the Act in §505 [21 U.S.C. §355] gives the Food and Drug Administration the authority to require approval prior to the marketing of statutory "new drugs." The new drug procedures require an opportunity for a hearing as well as judicial review based upon a "substantial evidence" standard. Similarly, every factual agency determination which is directed by the statute which may have the result of adversely affecting and imposing sanctions on members of the public is governed by either the §701(e) procedures or a separate and specific statutory hearing and judicial review structure.

To allow Appellees to promulgate substantive prescription regulations which have the effect of withdrawing products from the market without a hearing and, as claimed by Appellees without an evidentiary standard upon judicial review, is thus totally inconsistent with the framework of the statute. Congress in the Federal Food, Drug, and Cosmetic Act clearly recognizes that factual questions involving the public health and safety must be resolved on the basis of the factual evidence and not by mere dictation of agency policy. */

The District Court seeks to bolster its argument in support of substantive authority under §701(a) by citing "a considerable body of administrative practice." (JA 379a). The cited regulations under §701(a) relate to recent agency action which are in effect contemporaneous with the instant agency Statement of Policy. Only one of these has thus far been the subject of judicial comment as to substantive or interpretive status. As noted by the District Court the good manufacturing practice regulations were held by Judge Doyle to be interpretive in the sense of not having automatic and decisive effect, and

*/ The District Court's citation of Weinberger v. Hinson, Wescott & Dunning, 412 US 609 (1973) at JA 379a, is misplaced. That case involved a purely legal question as to whether the agency was required to hold the statutory formal hearing where no evidence of adequate and well controlled studies was presented by an applicant to show the safety and effectiveness of a "new drug." The court held that the statute did not require such a hearing in the absence of such evidence and that the agency interpretation of the statute was therefore correct.

requiring full proof by both sides. (JA 389a, Add. A10)

It should also be noted that the apparent agency policy during the last few years has been and continues to be to promulgate regulations which have the appearance of being substantive irrespective of the statutory procedures. For example, the agency has recently promulgated a proposal pursuant to the purported authority of §701(a) of the Act with respect to the vitamin content of so-called breakfast drinks. 39 F.R. 20895 (June 14, 1974). Although two specific provisions of the Act govern the labeling and composition of vitamin enriched products and standards of identity and both require the agency to proceed in accordance with §701(e) of the Act, the agency chose instead to proceed under §701(a). Similarly, with respect to nutritional labeling regulations which had formerly been handled by the agency pursuant to the §701(e) procedures, the Commissioner noted:

"The Commissioner realizes that legal challenge may be brought against the new approach to nutrition labeling in 21 C.F.R. 1.17. If 21 C.F.R. 1.17 is found invalid for any reason it will be necessary to resume the labeling of foods with added nutrients, or for which nutritional claims are made, under 21 CFR Part 125. The Commissioner is therefore keeping the record on this portion of the hearing open, for this limited purpose, in the event that it becomes necessary to amend this tentative order or to issue a supplemental tentative order to provide for labeling of this type pursuant to 21 CFR Part 125 in lieu of 21 CFR 1.17." 38 F.R. 2148 Col. 2 and 3, January 19, 1973.

It is apparently the policy of the agency to avoid wherever possible the hearing requirements which are so per-

sistently imbedded in the Federal Food, Drug, and Cosmetic Act. Despite such statutory hearing requirements, the agency's new policy is to opt in the first instance for a §701(a) type regulation in the apparent hope of avoiding the factual burdens and standards of §701(e) proceedings. The final element in this policy appears to be the agency position in the instant case that upon a declaratory challenge to a §701(a) agency action, there is no right to an evidentiary review of the agency action.

Appellant's respectfully submit that in accordance with both the legislative history of the prescription statute and the legislative history of the general regulatory authority under §701 of the Federal Food, Drug, and Cosmetic Act the instant Statement of Policy concerning Vitamins A and D is precisely what it purports to be - an interpretive statement of policy as to the application of the prescription statute with respect to Vitamins A and D.

Clearly, it was the intent of Congress to preserve a full right of trial in the courts with respect to such an interpretive Statement of Policy. As discussed under Point II of this brief, Appellees' motion for summary judgment as to the Statement of Policy was unwarranted under the facts of the instant case.

POINT IV

THE DISTRICT COURT IMPROPERLY GRANTED
APPELLEES' MOTION FOR SUMMARY JUDGMENT
BECAUSE THE RECORD FILED BY THE AGENCY
DOES NOT CONTAIN SUBSTANTIAL EVIDENCE
TO SUPPORT THE AGENCY ACTION

Appellants have previously noted that in the absence of a legislative grant of power and in light of the legislative history of the prescription statute, the Appellees do not have the authority to issue substantive regulations with respect to prescription requirements. If, however, this Court should hold that the instant agency action is indeed a substantive regulation, it is respectfully submitted that applicable scope of review precluded the granting of Appellees' motion for summary judgment.

The scope of review for substantive rule-making is set forth as follows:

"5 U.S.C. §706...The reviewing court shall --

* * *

(2) hold unlawful and set aside agency action, findings and conclusions found to be --

* * *

(E) unsupported by substantial evidence in a case subject to section 556 and 557 of this title or otherwise required to be reviewed on the record of an agency hearing required by statute."

In Citizens to Preserve Overton Park v. Volpe, 401

U.S. 402 (1971), the court stated:

"Review under the substantial evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself, 5 U.S.C. §553 (1964 Ed.Supp.v), or when the agency action is based on a public adjudicatory hearing." See 5 U.S.C. §§ 556, 557 (1964 ed.Supp.V). 401 U.S. at 414. */ (emphasis added)

As the Court states, all rule-making made pursuant to 5 U.S.C. §553 is governed by the substantial evidence standard. Since ~~Appellees~~ claim that the instant action is an exercise of substantive rule-making involving a record compiled pursuant to 5 U.S.C. §553, the scope of review must, under their theory, be the substantial evidence standard which governs all such substantive rule-making. The application of that standard requires an examination of the "record" to determine if there is substantial evidence to support the agency action with respect

*/ In fact, in Overton Park the Court held that the substantial-evidence standard did not apply because "[t]he Secretary's decision...was plainly not an exercise of a rule-making function." 401 U.S. at 414

to vitamins A and D.

Appellants respectfully submit that Appellees' motion for summary judgment should be denied under the foregoing principles because the "record" does not contain substantial evidence to support the agency action. At the very least, an imposition of a prescription requirement for specified dosage levels of vitamins A and D requires an analysis of the existing medical knowledge concerning these products, a determination as to the existence of a danger level, and a consequent selection of prescription levels based on appropriate consideration of the evidence and application of the standards in the prescription statute.

In terms of these evidentiary standards, a review of the record shows that there are two categories of comments which were submitted to the agency:

(a) Comments expressing opinions as to the propriety or legality of the prescription limitations; and

(b) Comments presenting analysis of the medical knowledge in relationship to the proposed prescription limitations.

The first category includes the thousands of letters and statements filed in opposition as well as the conclusory opinions

from some sources in support of the agency action. The second category includes only submissions in opposition to the proposal. No detailed analysis of the medical literature was submitted to the agency in support of the proposed restrictions. Every analysis of the literature found that the prescription levels established by the agency were unsupportable.

The reply affidavit of Dr. Joseph John Vitale, Professor of Community Medicine and Pathology, states that the prescription limitations set by the agency are unreasonable and also notes:

"The letters submitted by the Food and Drug Administration do not constitute scientific evidence contrary to the statements I have just made. For example, the letter of January 22, 1973 of Dr. George Mann (Exhibit D) contains no supportive references or rationale for his singular conclusion that all vitamins shall be put on a prescription requirement....To the same effect, the other letters submitted by the FDA do not constitute scientific evidence of toxicity or danger at any levels which are being discussed in the present regulation." (JA 94a)

It does not require expert testimony, however, to conclude that such letters of opinion are not substantial evidence in support of the agency action. Clearly, more is required than an unexplained endorsement of the proposed agency restriction.

It is, of course, theoretically possible, that the

Food and Drug Administration does have evidence and analysis in its possession to support the instant regulation. Clearly, however, it is not contained in the "record." If the agency wishes to limit Appellants to the "record," it too must accept the same limitation. */

The lack of substantial evidence is even more striking in terms of the specific requirements of the prescription statute. There is nothing in the record which can be said to be evidence that vitamins A and D at the levels specified are "not safe for use except under the supervision of a practitioner licensed by law." 21 U.S.C. §353(b)(1)(B). Similarly, there is no evidence to support the agency's failure to distinguish between infants, children and adults in applying the above standard in terms of appropriate dosage levels.

It is therefore apparent that if the agency action

*/ It must also be remembered that the lower court denied Appellants the right to discover the nature of the evidence and factual analysis which was before the agency in proposing the prescription levels for vitamins A and D. The "whole record" was therefore not before the court. The requirement for review of the "whole record" is discussed infra in connection with the "arbitrary or capricious" standard. The same considerations apply if the "substantial evidence" standard is applied.

herein is to be considered a substantive rule-making function, the "record" which the lower court established as the basis for review does not contain the requisite substantial evidence to support such a substantive determination. The citation in the proposed Statement of Policy to an unanalyzed list of medical articles cannot serve as a substitute for substantial evidence. As noted in Portland Cement Association v. Ruckelshaus, 486 F.2d 375 (D.C.Cir. 1973):

"In this connection, a comment on the proper use of scientific literature may be in order. If such literature is relied upon, the agency should indicate which particular findings of that literature are significant. A generalized reference, to a work as a whole, will avail the agency little if a problem arises on judicial review. On remand, any findings in the literature that are relied on by EPA should be specifically indicated." Id. at 400

No such analysis or specific reliance was ever attempted in the instant case and these unevaluated articles cannot be deemed evidence in support of the agency's position. Appellants respectfully submit that in the absence of such evidence in the "record," Appellees' motion for summary judgment should have been denied.

POINT V

THE DISTRICT COURT IMPROPERLY GRANTED
APPELLEES' MOTION FOR SUMMARY JUDGMENT
BECAUSE THE "WHOLE RECORD" WAS NOT
PRESENTED TO THE COURT FOR DECISION AND
BECAUSE THE INSTANT AGENCY ACTION IS
ARBITRARY AND CAPRICIOUS

The decision of the District Court utilized the narrowest concept of judicial review in upholding the validity of the agency action with respect to vitamins A and D. The standard urged by Appellees and adopted by the District Court is that the agency action is to be set aside only if it is found to be "arbitrary and capricious." 5 U.S.C. §706(2)(A)

It has already been noted that this standard has no applicability to the instant case. In Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971), the "arbitrary or capricious" standard was held applicable to substantive, non-rulemaking agency action. The instant case, however, involves either an interpretive non-binding agency policy statement (as contended by Appellants requiring a full trial or substantive rule-making (as contended by Appellees) which is governed by the "substantial evidence" standard.

Even under the "arbitrary or capricious" standard, however, there was no basis in the instant action for summary judgment in Appellees' favor. The nature of this scope of

review was clearly spelled out in the leading case of Citizens To Preserve Overton Park v. Volpe, supra, where the Court refused to apply the substantial evidence test because rule-making was not involved. The Court noted:

"[T]he court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." 401 US at 415

* * *

"That review is to be based on the full administrative record that was before the Secretary at the time he made his decision. But since the bare record may not disclose the factors that were considered or the Secretary's construction of the evidence it may be necessary for the District Court to require some explanation in order to determine if the Secretary acted within the scope of his authority and if the Secretary's action was justifiable under the applicable standard." 401 US at 420 (emphasis added)

Similarly, other courts have insisted that the whole record be presented in order to allow proper review. In Appalachian Power Co. v. Environmental Protection Agency, 477 F.2d 495 (4th Cir., 1973), the Court, relying on Overton Park, said:

"And when this Court reviews the action of the Administrator, it does not confine itself to the order of the Administrator or to the bare language...nor will it seek to determine from

the four corners of those two documents whether the action taken was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.' If judicial review were to be tethered to these abbreviated documents, it would 'almost inevitably become[s] a meaningless gesture' and would be reduced to 'a game of "blind man's bluff"'. [sic] Courts require that administrative agencies 'articulate the criteria' employed in reaching their result and are no longer content with bare administrative ipse dixits based on supposed administrative expertise.... While an agency may have discretion to decide, '[D]iscretion to decide does not include a right to act perfunctorily or arbitrarily'; and, in order for a Court to make a critical evaluation of the agency's action and to determine whether it acted 'perfunctorily or arbitrarily,' the agency must in its decision 'explicate fully its course of inquiry, its analysis and its reasoning'.... And, in making its review, the Court must have, not merely that full articulation of the agency's reasoning, but it must also have 'the whole record' on which the agency acted, or, as it is expressed in Overton Park, 'the full administrative record that was before the Secretary at the time he made his decision.'" 477 F.2d 495 at 506-507 (emphasis added) (citations omitted)

In Natural Resources v. E.P.A., 478 F.2d 875 (1st Cir. 1973), the Court again insisted on having the full record which was before the agency:

"There is no evidence that the data was ever collected....

[T]he judicial review provision necessarily confers authority to compel such information

from the E.P.A. to the extent needed to determine whether the Administrator's action is in accordance with law. See Citizens To Preserve Overton Park v. Volpe, 401 US 402...." 468 F.2d 875 (1st Cir., 1973) at 880-1

In Silva v. Lynn, 482 F.2d 1282 (1st Cir., 1973), the Court stated:

"In reviewing the final...decision to proceed with the plan as described therein, the district court considered only the final statement, the draft statement and comments filed thereto, certain affidavits and testimony taken in court. It refused appellants' requests that the administrative record be produced. This record contains the more detailed studies and background of deliberation which form the basis of the final EIS. We think that the law requires production of the entire administrative record. See Citizens To Preserve Overton Park v. Volpe, 401 U.S.402....

While there may be some instances in which the entire record need not be filed, where the correctness of factual findings are involved or where the complainants request the full record, we think the agency must produce it in court." Id. at 1283; Text and footnote

See also Bradley v. Weinberger, 483 F.2d 410 at 414 (1st Cir., 1973); Mobile Oil Corp. v. Federal Power Commission, 483 F.2d 1238 at 1259-1260 (D.C. Cir. 1973); Internat'l Harvester Co. v. Ruckelshaus, 478 F.2d 615 at 648-649 (D.C.Cir. 1973).

The insufficiency of the "record" filed by Appellees

below is made evident from the very inception of the instant agency action. On December 14, 1972, the Food and Drug Administration published its proposed Statement of Policy proposing the 10,000 and 400 I.U. prescription levels for vitamins A and D respectively. The only scientific support for this proposal was a reference to a listing of articles in the literature. The unevaluated articles alone cannot support the instant agency action. If no evaluation was made by the agency, surely the prescription restriction can only be categorized as arbitrary. This is especially true in light of the fact that no such evaluation supporting the restrictions was submitted by any member of the public.

If, on the other hand, such an evaluation was made it should have been made public originally. At the very least, it should have been placed before the District Court in order to allow a determination as to whether the agency's factual determinations were based upon a proper consideration of all the relevant factors.

Many relevant determinations are not included in the "record." It has already been noted that neither the original proposal or the final agency action herein speak in terms of the prescription statute requirement that the product be "not safe for use except under the supervision of a practitioner."

21 U.S.C. §353(b)(1)(B). Similarly, the "bare record" does not show how the margins of safety claimed by the Commissioner (38 F.R. 20724, col. 2-3, August 2, 1973) (JA 33a) were formulated. No explanation or justification is offered for the failure to distinguish between infants, children and adults in terms of the appropriate levels for prescription requirements. See 38 F.R. 20724, col. 1 (August 2, 1973) (JA 33a) Moreover, the Commissioner expressly states in the comments accompanying the final and proposed restrictions that the determinations were made on the basis of ex parte information available to the Commissioner, none of which is included in the "record." For example, the original proposal stated:

"Based upon the above considerations it is the opinion of the Food and Drug Administration and medical experts that Vitamin A in excess of 10,000 IU per dosage unit shall be dispensed only by prescription." 37 F.R. 26619, col. 1 (December 14, 1972) (emphasis added) (JA 36a)

Similarly, the final agency action notes:

"Based on consultation with the most knowledgeable experts available, the Commissioner finds that the scientific consensus is that the proposed limits are appropriate at this time." 38 F.R. 20724, col. 2 (August 2, 1973) (JA 33a)

The course of administrative conduct in this matter demonstrates that the decision of the Commissioner was not

based exclusively, or even primarily, on the record which the District Court established as the basis for review. The proposal of December 14, 1972 necessarily presumes a prior determination of appropriate prescription levels presumably on the basis of evidence and analysis which was before the agency. */ No part of this internal evidence or evaluation is included in the "record."

Instead, the agency published its conclusions and asked for the submission of comments. Ultimately, the agency adhered to its original internal evaluation of the evidence and analysis, which was never made public. No formal findings of fact have been made, and the actual basis for the agency's decision remains a matter of conjecture. **/

*/ In fact, even the letters received by the agency in support of the Statement of Policy appear to be based upon such a presumption. See e.g., JA 195a where one commentator notes that his organization "assumes" that the level chosen by the FDA is appropriate.

**/ It must also be remembered that the agency ignored the testimony on this subject at the vitamin hearings despite the fact that some of the comments expressly brought such testimony to the attention of the agency. (JA 172a)

By insisting in the face of the above that the record submitted by Appellees was complete (JA 386a), the District Court in effect was bound to find that the agency action herein was arbitrary and capricious. Surely, it cannot be said that the mere expression by an agency of its opinion as to a factual and technical matter, supported only by simple letter endorsements and contrary to every analysis presented to the agency, is sufficient even under the limited arbitrary or capricious standard. The District Court erred in not requiring a fuller presentation by the agency (as sought via Appellants notice of deposition) or, in the alternative, in not finding the instant agency action to be arbitrary and capricious and thus requiring denial of Appellees' motion for summary judgment.

POINT VI

THE DISTRICT COURT IMPROPERLY VACATED APPELLANTS' NOTICE OF DEPOSITION

The issues connected with Appellants' notice to take the deposition of Appellees with respect to the factual basis for the determination of the Statement of Policy concerning vitamins A and D is intimately and integrally related to the issues raised under the preceding Points of this brief as to

the proper scope of review. Appellants are at a loss to understand as to how the District Court found that the deposition sought involved "the mental process" of the Commissioner. The notice clearly specifies the factual inquiry which was sought. (JA 350a)

The propriety of the deposition is established on either of two grounds. First, the right to a deposition is inherent in the right to a full trial as discussed under Points II and III of this brief. Moreover, the woeful inadequacy of the "record" filed by the agency required some means of explicating the rationale and basis of the agency's action herein. See Angel vs. Butz, 487 F.2d 260 at 263 (10th Cir. 1973) where the court indicates that a deposition was taken in order to provide the missing agency rationale behind a regulation. Moreover, the Supreme Court of the United States in Citizens To Preserve Overton Park v. Volpe, supra, expressly held that:

"Examination of the decision makers is appropriate where the bare record is insufficient to show the full factual and policy basis behind an agency action."
401 US at 420

It is therefore respectfully submitted that the District Court erred in vacating Appellants' notice of deposition.

POINT VII

VITAMIN A AND D PRODUCTS CANNOT BE CLASSIFIED AS DRUGS WITHIN THE STATUTORY DEFINITION IN SECTION 201(g) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT [21 USC §321(g)] MERELY BECAUSE THEY CONTAIN QUANTITIES OF SAID VITAMINS IN EXCESS OF THAT CONSIDERED BY THE FOOD AND DRUG ADMINISTRATION TO BE NECESSARY IN HUMAN NUTRITION

Appellants respectfully wish to point out to the Court that there is one threshold question yet to be discussed and determined. The application of the prescription statute, as discussed in this brief, necessarily involves an initial determination that the products in question are "drugs." The statute, of course, authorizes prescriptions only for drug products. The statutory definition of the term drug must therefore be considered in terms of its applicability to the potencies of vitamins A and D involved in the Statement of Policy.

The original agency proposal with respect to vitamins A and D made no mention of drug classification for these products which had previously been considered as foods for special dietary use. As part of the final agency action on August 2, 1973, in response to objections and comments filed with the agency, the Commissioner sought to explain that these products were drugs under the statute because in his view such potencies were in excess of that needed in daily human nutrition. (JA 32a).

It should be noted that the identical theory as to drug

definition and the legal and factual objections thereto by Appellants are currently at issue before this Court in the pending case of NNFA and Solgar Co., Inc. v. FDA, Docket No. 73-2129. Involved is an express agency regulatory attempt to classify as drugs all vitamin products which exceed certain specified potencies. See 38 F.R. 20717, 21 CFR 125.1(h), August 2, 1973. To the extent that this Court reviews and determines the propriety of said attempted drug definition in the pending proceedings, it will of course be dispositive of the same issue in the instant case. If this Court should rule the drug definition invalid, then clearly the instant prescription requirement which is also premised thereon, must fall. Similarly, if this Court should uphold such drug definition, Appellants' argument with respect to this issue would be foreclosed on this appeal as well. There is no purpose in burdening this Court and counsel with a repetitive presentation as to the identical issue soon to be decided.

One of the issues, however, which was raised in the pending proceeding with respect to said drug definition, is this Court's lack of jurisdiction to review such drug definition because such definition was not properly a part of a §701(e) proceeding. It is therefore possible that this Court will not rule on the merits of said drug definition for lack of jurisdiction and that the issue would therefore be properly presented

in the instant case.

Oral argument in the pending proceeding before this Court was had on June 19, 1974. It is perhaps likely that a decision will be had therein prior to the time for argument in the instant case. Appellants would therefore merely note at this time that the issue of the propriety of the agency's "drug" definition will be addressed either in their reply brief or, with leave of the Court, in a supplemental brief.

CONCLUSION

The foregoing discussion has shown the impropriety of the District Court's granting Appellees' motion for summary judgment on various legal and factual grounds. The failure of the agency to comply with the statutory prescription requirements mandates a finding of the invalidity of the Statement of Policy as a matter of law. Alternatively, the presence of factual questions as to the propriety of the prescription levels established for vitamins A and D, and the basis for the agency's decision thereon, required a full trial in the District Court and, at the very least, an inquiry to establish the "whole record" which was before the agency. The vacating of Appellants' notice of deposition prevented the proper development of the

issues and facts below.

Appellants therefore respectfully submit that the ruling of the District Court should be reversed.

Respectfully submitted,

BASS & ULLMAN
Attorneys for Appellants

ADDENDUM

STATEMENT OF POLICY UNDER REVIEW

TITLE 21, CODE OF FEDERAL REGULATION - PART 3
ELEMENTS OF GENERAL POLICY OR INTERPRETATION: STATUS OF VITAMIN A AND D

Section 3.94 "(a) Vitamin A is an essential nutrient for humans. It is widely recognized that large amounts of vitamin A can cause adverse effects, some of which are serious. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin A is 1500 International Units, (IU) for infants, 2500 IU for children under 4 years of age, 5000 IU for adults and children 4 or more years of age, and 8000 IU for pregnant or lactating women.

"(b) In view of the toxicity of excessive consumption of vitamin A, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake are drugs subject to section 503 (b) (1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend.
'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by §1.106(b) (3) (i) of this chapter, and especially appropriate warnings regarding vitamin A toxicity.

"(c) Preparations containing 10,000 or less IU of vitamin A per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 10,000 IU."

Section 3.95 "(a) Vitamin D is an essential nutrient for humans. It is widely recognized that vitamin D, when ingested daily in large amounts, is toxic. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin D is 400 International Units (IU).

"(b) In view of the toxicity of the excessive consumption of vitamin D, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin D in excess of 400 IU per dosage unit or recommended daily intake are drugs subject to section 503(b) (1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend, 'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by §1.106(b) (3) (i) of this chapter, and especially appropriate warnings regarding vitamin D toxicity.

"(c) Preparations containing 400 or less IU of vitamin D per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 400 IU.

"(d) Foods which are represented for use solely under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption may contain vitamin D not in excess of 1000 IU per dosage unit or recommended daily intake."

ADDENDUM**FEDERAL FOOD, DRUG, AND COSMETIC ACT,
AS AMENDED****DEFINITIONS**

Section 201(g)(1) [21 USC 321(g)(1)]. The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

Misbranded drugs and devices
Section 502 [21 U.S.C. §352]

A drug or device shall be deemed to be misbranded—

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

Section 503 [21 U.S.C. §353]

Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(b) (1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except subsections (a), (i) (2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to sections 352(d) and 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

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REGULATIONS AND HEARINGS

Section 701(a) [21 USC 371(a)] The Authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

Section 701(e) [21 USC 371(e)] (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any

interested persons showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person

may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Section 701 (f) [21 USC 371 (f)] (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary the court may order such additional evidence (and

evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary of any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

5 U.S.C.

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule-making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(c) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule. Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383.

5 U.S.C.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. [The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error. Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

-v3-

Case No. 72-CR-109

EVERETT FISHERIES, INC.,
a corporation, and ERIC
E. JOHNSON, an individual,

Defendants.

DOCUMENT NUMBER	28
U. S. DISTRICT COURT WEST. DIST. OF WIS. - MADISON	
JUN 21 1973	
JOSEPH W. SHUPHEWITZ, CLERK	
CASE NUMBER	72-CR-109

STENOGRAPHIC TRANSCRIPT

of Ruling by the Court had upon hearing in the above-entitled criminal action in said court, sitting in the City of Madison, in said Western District and State of Wisconsin, the Honorable JAMES E. DOYLE, Judge, presiding, on Wednesday, the 30th day of May, 1973, at 10:45 a.m.

A P P E A R A N C E S

JAMES M. BABLITCH, Assistant United States Attorney, Madison, Wisconsin; CHARLES J. RAUBICHECK, Attorney-at-Law, Department of Health, Education & Welfare, Office of the Secretary, Rockville, Maryland, 20852 and THOMAS S. BRETT, Attorney-at-Law, U. S. Department of Justice, Washington, D. C., 20530, appeared on behalf of the plaintiff.

JOHN C. FRITSCHLER, Attorney-at-Law, 222 South Hamilton Street, Madison, Wisconsin, 53703, appeared on behalf of the defendants.

P R O C E E D I N G S

(Whereupon, Ruling by the Court was made in the above-entitled criminal action at 10:45 o'clock a.m. as follows:)

THE COURT: I will make certain assumptions for the purpose of the Ruling. I will assume for the purpose of this Decision that 21 CFR 128a, Subpart A is a regulation which the Secretary was authorized to promulgate pursuant to 21 U.S.C. Section 371 (a) and also that the regulation was duly promulgated in terms of all procedural requirements.

Also for the purpose of the Ruling I will assume that the regulation is not arbitrary or unreasonable but on the contrary that it is a regulation "for the efficient enforcement of this Chapter" within the meaning of Section 371 of Title 21 of the United States Code.

I understand that the precise question to be decided, that is, the precise question which I intend to decide presently is whether a defendant is guilty of a violation of — Strike that.

The precise question on which I intend

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to rule is whether these defendants are to be held guilty of the offense charged against them in each of the three counts of the information and, specifically, whether they are to be found guilty of a violation of Section 331 (a) of Title 21 of the United States Code as a matter of law if the government can prove beyond a reasonable doubt that the defendants violated one or more of the provisions of Section 128a, Subpart A of Title 21 of the Code of Federal Regulations. I decide that the answer to that question is "No".

It is quite clear that the Congress has nowhere provided that it shall be a crime to violate a regulation such as 21 CFR 128a, Subpart A which I have assumed to have been validly promulgated under 21 U.S.C. 371.

The government's contention is, as I understand it, that in administering this criminal prosecution the finder of fact, whether it be a jury or a judge, is to be found to find the defendant guilty as charged and to find that the food introduced into commerce in each case was adulterated within the meaning of 21 U.S.C. Section

342 (a) (4) if it is shown beyond a reasonable doubt that the food was prepared in a manner which violated in any respect any provision of Subpart A of Section 128a of the Regulations.

I believe that in every criminal case under the sections of the statutes involved here the government must prove beyond a reasonable doubt that the food in question was adulterated and that it was prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health. And I conclude that in every criminal prosecution under these sections the government must satisfy the finder of fact under proper instructions that these conditions existed.

I conclude that in each case the government must present its evidence so as to persuade the finder of fact and the defense must have its opportunity to dispute and that the judgment exercised by the Food and Drug Administration in promulgating regulation 128a, Subpart A is not to be given automatic and decisive effect in the case; rather, that the regulations in question

are to be given just such effect as the trier of fact may consider that they deserve on the basis of the evidence in the case.

That completes my ruling with respect to that point; and it will be the rule that will apply to further proceedings and the trial in the case.

The defendants have moved to dismiss the information for vagueness. I will declare now that I intend to apply the statute in the case in a manner which other courts have held saves it from vagueness, that is, I will administer the case in such a way that the government will be required to prove beyond a reasonable doubt that the conditions under which the fish was prepared, packed or held were insanitary conditions whereby it may have been rendered injurious to health in the sense that those conditions gave rise to the reasonable probability of contamination. So construed, I hold that the statute is not vague and the motion to dismiss is denied.

I believe that completes my Ruling.

THE COURT: It is ordered then that within ten days counsel for the defendant is to submit a letter to the Court with a copy to opposing counsel stating those matters of discovery, if any, on which the defendant desires a ruling by the Court.

• • •

THE COURT: I will order that on or before June 8, 1973, the government submit a letter to the Clerk of the Court with a copy to opposing counsel stating whether the government would agree to a trial to the Court without a jury. And, Mr. Clerk, I would request that you consider a possible trial time in July and issue a notice of trial to counsel. And, of course, if it should turn out that the specific time indicated by the Clerk is not convenient for some reason, if counsel will consult with the Clerk you could adjust the trial time.

Mr. Bablitch, is there anything further you wish to raise presently?

MR. BABLITCH: No, Your Honor.

Thank you.

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THE COURT: Mr. Fritschler?

MR. FRITSCHLER: No, sir.

Thank you.

THE COURT: Very well. The court
will recess until one o'clock.

3 3 3

(11:06 o'clock a.m.)

CERTIFICATE

I, LORETTA PETERS, Official Court Reporter for the United States District Court in and for the Western District of Wisconsin, hereby certify that as such official reporter I was present in said court throughout its sessions, held in the City of Madison, in said Western District and State of Wisconsin; on Wednesday, the 30th day of May, 1973; that I then and there reported by machine shorthand the proceedings had upon hearing then and there held in the above-entitled criminal action; that I thereafter caused to be prepared, under my personal direction, the foregoing typewritten transcript of said proceedings from my original stenographic notes thereof, so taken at said time and place; that the above and foregoing is a full, true and complete transcript of said Ruling by the Court at said time and place, and is the official transcript thereof.

Loretta Peters

AMERICAN PHARMACEUTICAL
ASSOCIATION et al.,

Plaintiffs,

v.

CASPAR W. WEINBERGER
et al.,

Defendants.

Civil Action No. 1485-73

FILED

JUN - 6 1974

JAMES E. DAVEY, Clerk

OPINION AND ORDER

This is an action for judicial review of a regulation of the Food and Drug Administration (FDA) which restricts the distribution of methadone to certain specified outlets as set forth in the regulation. In effect, it prohibits virtually all licensed pharmacies from dispensing this drug when lawfully prescribed by a physician, despite the fact that methadone was invented and was first used as a safe, useful and effective agent in the treatment of severe pain and for antitussive purposes. Decision is not made easier by the fact that in recent years methadone has become a widely known maintenance agent in the treatment of heroin addicts and there is evidence of serious abuses in the distribution of this drug. In their efforts to control improper distribution of methadone, there are strong public policy arguments on the side of defendants. At the same time, the popularity of methadone for use as a pain killer has declined because of the introduction of effective new drugs, and as recently as 1972 the plaintiff Association formally recommended that FDA withdraw its approval of methadone for its indications as an analgesic and antitussive and expressed its philosophic non-disagreement with a course of regulation which would restrict the distribution and use of methadone to approved methadone treatment programs.

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The challenged regulation, while ruling out most so-called community pharmacies in the dispensing of methadone for any purpose, still permits approved hospital pharmacies to dispense methadone for analgesic and antitussive purposes. Stripped of the rhetoric which abounds in the papers before us, this appears to be the basis of plaintiffs' complaint. Whether the FDA has the authority to enact the challenged regulation depends on the interplay and connection between two complementary but distinct statutes, the Food, Drug and Cosmetic Act of 1938 and the Comprehensive Drug Abuse Prevention & Control Act of 1970 and the respective roles assigned by Congress to the agencies which administer these Acts. With this brief background, we proceed to the issues presented.

This cause came on for hearing on defendants' motion to dismiss, or in the alternative, for summary judgment and plaintiffs' cross-motion for summary judgment on May 8, 1974. Plaintiffs challenge the validity of certain provisions of the Food and Drug Administration's methadone regulations, 21 C.F.R. §130.44 ("Conditions for use of methadone") and §130.48 ("Drugs that are subjects of approved new-drug applications and that require special studies; records and reports.")^{1/} Specifically, plaintiffs object to those parts of the regulations which purport to restrict the distribution of methadone to direct shipments from the manufacturer to (a) approved maintenance treatment programs, (b) approved hospital pharmacies, and (c) in cases where hospital pharmacies are unavailable in a particular area, to selected community pharmacies.^{2/}

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Plaintiffs include the American Pharmaceutical Association (APhA), a professional association of pharmacists with a membership in excess of 50,000, three individual professional pharmacists and an individual physician. They argue that the restrictions imposed on the channels of distribution exceed the limits of FDA's authority, were promulgated on the basis of an inadequate record and, being discriminatory in several respects, violate the due process clause of the Fifth Amendment. Plaintiffs seek declaratory relief holding said restrictions invalid and enjoining defendants from enforcing them.

Defendants are the Secretary of Health, Education and Welfare, the Commissioner of Food and Drugs, the Attorney General and the Acting Administrator of the Drug Enforcement Administration. They counter plaintiffs' contentions by citing FDA's authority under the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. §301 et seq., to control access to the public market of all new drugs (21 U.S.C. §335) and to promulgate regulations for the efficient enforcement of the Act (21 U.S.C. §371(a)) and their authority under the Comprehensive Drug Abuse Prevention & Control Act of 1970 (Pub. L. 91-513, 84 Stat. 1241) "to determine the appropriate methods of professional practice in the medical treatment of ... narcotic addicts...." (42 U.S.C. §257a)^{3/} With respect to plaintiffs' contention that the regulations in question constitute arbitrary and capricious action not supported by the administrative record, defendants note what they argue is "ample evidence" to support the regulation's restrictions on methadone distribution. See defendants' Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment, pp. 22-29. Finally, in answering plaintiffs' due process challenge, defendants urge that they

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need only demonstrate a rational basis for the regulations in order to satisfy the Constitution and that the classifications in issue are unquestionably rationally based in the purposes of the enabling statute. Since the Court concludes that the regulation exceeds the limits of FDA's statutory authority insofar as it purports to restrict the channels of distribution for a drug which is not deemed solely investigational, the Court need not address plaintiffs' latter two arguments.

I.

The drug methadone, a synthetic substitute for morphine, is a "new" drug within the meaning of section 201(p) of the Federal, Food Drug and Cosmetic Act, 21 U.S.C. §321(p) and, as a new drug, requires FDA's approval of a NDA, filed with the Commissioner of Food and Drugs pursuant to section 505(b) of the Act, 21 U.S.C. §355(b). The drug was first approved by FDA in the 1950's as safe for use as an analgesic and antitussive agent as well as for short-term detoxification of persons addicted to heroin. Subsequently, investigation of methadone for use in long-term maintenance of narcotic addicts (methadone maintenance) was approved by FDA pursuant to its authority under 21 U.S.C. §355(i), the investigational-new-drug (IND) exemption. Section 355(i) of the Act empowers FDA to exempt from NDA approval requirements those new drugs "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Final guidelines for long-term maintenance programs were promulgated by FDA in 1971. 36 Fed. Reg. 6075 (1971). A year later FDA determined that "retention of the drug [methadone] solely on an investigational status appears to be no longer warranted" (37 Fed. Reg. 6940) and published a notice of proposed rulemaking which resulted, with certain modifications, in the regulations now in question.

The final regulation gave notice that pursuant to FDA's authority under 21 U.S.C. §355(c), the Commissioner was withdrawing approval of all outstanding NDA's because of "a lack of substantial evidence that methadone is safe and effective for detoxification, analgesia, or antitussive use under the conditions of use that presently exist."^{5/} 37 Fed. Reg. 26794 (1972). Having withdrawn all approved NDA's, the Commission's new regulatory scheme is presently the exclusive means of distribution for the drug methadone. The Commissioner has thereby created an admittedly unique classification for methadone since on the one hand he has determined that methadone should not be limited solely to investigational status while at the same time concluding that the drug is inappropriate for regular NDA approval. As statutory support for this novel solution to the methadone dilemma, defendants rely on an expansive interpretation of the Commissioner's NDA authority under §355 of the Act.

II.

Under the Federal Food, Drug and Cosmetic Act, the FDA (through the Secretary of HEW) has the responsibility of passing on the merits of NDA's. The grounds upon which an NDA can be denied approval are explicitly stated in subsection (d) of §355 and the NDA shall be approved "if [FDA] ... finds that none of the grounds for denying approval ... applies." 21 U.S.C. §355(c). The NDA must be supported by "substantial evidence" defined to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could be fairly and responsibly concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. §355(d).

One of the six enumerated grounds for refusing approval of a new drug application (NDA) specifically deals with the "methods" or "controls" used in connection with the proffered drug. Subsection (d)(3) of §355 reads as follows:

(d) If the Secretary finds

* * *

- (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

* * *

he shall issue an order refusing to approve the application. (Emphasis supplied)

This is the only provision of §355 which speaks of the Secretary's authority with respect to "controls." The Congress apparently intended that the Secretary, or his delegate, FDA, be responsible for the adequacy of pre-marketing methods and controls inasmuch as the provision delineates the scope of the provision to the manufacturing, processing and packaging stage of a drug's genesis.

The defendants point out, however, that §355(d) also gives the Secretary the authority to refuse to approve an NDA where the reports of the investigations submitted do not include adequate tests showing whether the new drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. §355(d)(1). See also 21 U.S.C. §355(d)(2) and (4). Defendants argue that the term "safe"^{6/} should be interpreted with reference not only to the inherent qualities of the drug under consideration but also in the sense of the drug's being secure from possible misuse. Such a broad interpretation would, according to defendants' theory, serve as the statutory foundation for FDA's exercise of authority in restricting methadone's channels of

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distribution because FDA's principal rationale for restricting distribution was "to help reduce the likelihood of diversion." 37 Fed. Reg. 26790 (1972).

As a general proposition of statutory construction, a general term should not be construed in isolation but should be interpreted according to the context of the statute within which it is found.^{7/} As noted above, the term "safe" is used in conjunction with the phrase "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." When taken in this context, a determination of whether a drug is "safe" is premised on the drug's use in the "prescribed, recommended, or suggested" manner. Thus the context of the statute indicates that the term "safe" was intended to include only the inherent safety of the drug when used in the manner intended. Moreover, as also noted above, the subject of "controls" is specifically covered in provision (3) of the same subsection (d) wherein the term "safe" appears. Provision (3) extends the Secretary's authority to pass on the adequacy of methods, facilities and controls only with respect to manufacturing, processing and packaging. Under the doctrine of "expressio unius est exclusio alterius"^{8/} any stage of the drug's genesis not specifically mentioned in provision (3) was presumably intended to be excluded from the Secretary's authority. Thus by examining the term "safe" in the context of those provisions of the Act in which it appears as well as in relationship to the provision of the Act which specifically deals with controls, the Court concludes that the term "safe" was intended to refer to a determination of the inherent safety or lack thereof of the drug under consideration when used for its intended purpose.^{9/}

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Finally, the legislative history of the Act fully supports this conclusion. In enacting the Comprehensive Drug Abuse Prevention and Control Act of 1970, Congress was presented with a conscious decision as to how the lines of authority should be drawn with respect to the regulation of dangerous drugs. Congress decided to continue all control authority over the distribution of dangerous drugs in the Justice Department despite a recommendation of the Prettyman Commission that this function be transferred to HEW.^{10/} The House Committee on Interstate and Foreign Commerce in their report on the Comprehensive Drug Abuse Prevention and Control Act of 1970 indicated that Title II of that Act, known as the Controlled Substances Act, was designed to "provide authority for the Department of Justice to keep track of all drugs subject to abuse manufactured or distributed in the United States in order to prevent diversion of these drugs from legitimate channels of commerce."^{11/} Although it is nowhere specifically stated that Congress contemplated that the Justice Department would have exclusive authority to prevent diversion, this result would appear logically to follow from a comparison of the functions delegated to the Secretary of HEW with those assigned to the Attorney General.

III.

In addition to being a "new" drug and thus within the jurisdiction of the FDA, methadone is a controlled substance within Schedule II of the Controlled Substances Act, 21 U.S.C. §812. Under this Act the Attorney General is made responsible for the registration of any person who manufactures, distributes or dispenses any controlled substance. 21 U.S.C. §822. An applicant may be refused registration if the Attorney General makes a determination that registering the applicant would be

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exemption is approved, the Commissioner may, of course, severely restrict the distribution of the exempted drug to bona fide researchers and clinicians. But once a drug is cleared for marketing by way of a NDA-approval, for whatever uses the Commissioner deems appropriate, the question of permissible distribution of the drug, when that drug is a controlled substance, is one clearly within the jurisdiction of the Justice Department. The diversion of the particular drug to a use not approved by the Commissioner would be grounds for revocation of the offending distributor's registration.^{14/} FDA attempts to accomplish preemptorily by way of its challenged regulation, that which could only be accomplished, according to the scheme of the Controlled Substances Act, by way of show-cause proceedings initiated by the Attorney General, i.e., revoking the authority of otherwise duly-registered distributors with respect to the drug methadone. To allow the challenged portions of the methadone regulations to stand, therefore, would be to abrogate the collective judgment of Congress with regard to the appropriate means of controlling unlawful drug diversion.

This is particularly true of the regulations' denial of authority to the plaintiffs at bar. Although the Attorney General generally has discretion to register applicants wishing to distribute or dispense controlled substances, 21 U.S.C. §823(b), in the case of "practitioners"^{15/} the Attorney General must register them "if they are authorized to dispense under the law of the State in which they regularly conduct business." 21 U.S.C. §823(f). Congress has thereby specifically sanctioned the registration of all State-licensed practitioners with the clear intent of permitting them to dispense controlled substances on an equal basis with all other approved distributors. In the face of such clear-cut Congressional intent, it would be anomalous to suggest that an agency, by the mere issuance of a regulation, could modify these mandated channels of distribution. Accordingly, the Court concludes

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inconsistent with the public interest. ^{12/} Congress has also provided the specific means for revoking or suspending the authority of a registrant to distribute controlled substances. Section 824 of Title 21 enumerates three grounds upon which the Attorney General may act:

(a) A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Attorney General upon a finding that the registrant--

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance; or

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances. ^{13/}

In addition, Congress has specified the precise procedure to be followed by the Attorney General in attempting to revoke or suspend a registration. 21 U.S.C. §824(c).

The Court concludes that Congress intended to create two complementary institutional checks on the production and marketing of new drugs. At the production or pre-marketing stage, the FDA is given the primary responsibility in determining which new drugs should be permitted to enter the flow of commerce. The Commissioner must approve or deny every NDA, or he may determine that a particular new drug qualifies for IND status in order to permit additional experimentation. When an IND

that FDA has overstepped the bounds of its authority in purporting to limit the distribution of methadone in the manner contemplated by its regulations.

IV.

It is undoubtedly true that methadone poses unique problems of medical judgment, law enforcement and public policy but this fact alone cannot justify a federal agency of specifically delimited jurisdiction from implementing equally unique control solutions not authorized by Congress. The problem of unlawful diversion is one presently consigned by Congress to the Drug Enforcement Administration (DEA, formerly the Bureau of Narcotics and Dangerous Drugs) of the Department of Justice. FDA, on the other hand, has the responsibility of making the initial decision, based on all available medical and scientific data, as to whether a particular new drug is safe and effective for its intended use. While the functions of FDA and DEA are not entirely exclusive of one another,^{16/} a certain division of authority and responsibility was clearly intended by Congress and must be recognized by this Court in order to preserve the integrity of the legislative scheme. Under these circumstances, the relative merits of FDA's plan to control the distribution of methadone, a controlled substance, must first be passed upon by Congress.^{17/}

WHEREFORE, for all the foregoing reasons, it is this 5th day of June, 1974,

ORDERED, that plaintiffs' motion for summary judgment be, and the same hereby is, granted; and it is

FURTHER ORDERED, that defendants' motion to dismiss, or in the alternative, for summary judgment be, and the same hereby is, denied.

Order to be settled on notice.

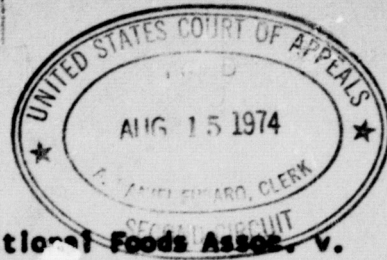
- 1/ The Commissioner of Food and Drugs published the notice of proposed rule making on April 6, 1972. 37 Fed. Reg. 6940-46. The final methadone regulations were promulgated on December 15, 1972. 37 Fed. Reg. 26790-26807. Some portions of the regulation became effective on that date and the remainder became effective March 15, 1973.
- 2/ 21 C.F.R. §130.44(f)(4) reads:
Shipments to remote areas. In remote areas or in certain exceptional circumstances where there are no approved hospitals, community pharmacies may be approved by the Food and Drug Administration to receive shipments of methadone for administering or dispensing for analgesia upon the recommendation of the State authority and after consultation with the Bureau of Narcotics and Dangerous Drugs. In addition, community pharmacies are permitted to serve as dispensing facilities for out-patient subjects in connection with approved methadone treatment programs (37 Fed. Reg. 26790) and wholesale pharmacy outlets may in some instances receive and stock methadone for trans-shipment to approved dispensers. 21 C.F.R. §130.44(j)(1).
- 3/ At oral argument counsel for the defendants relied solely on FDA's authority under the new drug approval (NDA) provisions of the Act, specifically 21 U.S.C. §355(d) which lists among the grounds for refusing approval of an NDA a finding that the new drug is either unsafe for use under the conditions prescribed or has not been proven to be safe under such conditions. Accordingly, the Court will not specifically address the position taken by defendants in their memoranda that the challenged portions of the regulation rest on FDA's combined authority under both the NDA and the investigational-new-drug (IND) provisions of the Act set forth in 21 U.S.C. §355(i).
- 4/ The functions vested in the Secretary of the Department of Health, Education and Welfare by the Federal Food, Drug and Cosmetic Act have been delegated to the Commissioner of Food and Drugs. 21 C.F.R. §2.120.
- 5/ Although the Commissioner notes a lack of evidence with respect to methadone's effectiveness for the enumerated uses, defendants have relied exclusively on the drug's alleged safety hazard in attempting to justify the challenged restrictions on distribution.
- 6/ The term "safe" is defined by section 321(u) of the Act as referring to the "health of man or animal." This definition is not directly made applicable to §355 but because it is made applicable to the definition of "new drug" it would seem to be applicable by implication to §355. Although the definition is itself ambiguous, in the context of the Act it tends to support the Court's conclusion.

- 7/ See, e.g., Sutherland Statutory Construction 47.01 (Sands, 4th ed. 1973).
- 8/ Id. at §47.23.
- 9/ Even if the Court were to agree with defendant's interpretation of the term "safe," this alone would not provide a statutory basis for the regulations challenged herein. At most such an interpretation would authorize FDA to deny or withdraw any methadone NDA based on a finding that the drug could not be "safely" distributed. As outlined in the Court's opinion, FDA's discretion under the Act's NDA provisions is limited to either approving or denying NDA's and nowhere is FDA empowered to approve an NDA upon the condition that the drug be distributed only through specified channels.
- 10/ Recommendation No. 9, Advisory Commission on Narcotics & Drug Abuse, reprinted in H. Rep. No. 91-1444 (pt. 1), 91st Cong., 2d Sess. 16-20 (1970).
- 11/ H. Rep. No. 91-1444 (pt. 1), supra at 22.
- 12/ "In determining the public interest, the following factors shall be considered:
- (1) The maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
 - * * *
 - (3) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
 - (4) Past experience in the distribution of controlled substances;" (21 U.S.C. §823(b))
- 13/ 21 U.S.C. §824(a).
- 14/ Id. Although revocation stemming from unlawful diversion is a somewhat cumbersome process under the current standards of §824(a), Congress has recently taken the initiative in supplementing DEA's authority in this respect. See note 17 supra.
- 15/ 21 U.S.C. §802(20) defines the term "practitioner" to include, inter alia, a physician, scientific investigator, pharmacy or "other person licensed ... to distribute ... a controlled substance in the course of professional practice or research."

16/ For example, the Attorney General, in exercising his authority under 21 U.S.C. §811(a) to add or remove drugs from the schedules of controlled substances established by the Controlled Substances Act, must first call upon FDA for its recommendation. The recommendations of FDA, insofar as they concern "scientific and medical matters" relating to the "appropriate schedule, if any, under which such drug or substance should be listed" are binding on the Attorney General. 21 U.S.C. §811(b).

17/ In a related effort to streamline the enforcement authority of DEA, both Houses of Congress recently passed a proposed amendment to the Controlled Substances Act. Specifically, the amendment gives the Attorney General expanded authority to require special registration of those practitioners who dispense or administer narcotic drugs in connection with treatment programs and to preemptorily revoke such registration in the event that a particular registrant fails to comply with the drug security standards imposed by the Attorney General. See H. Rep. No. 93-884, 93d Cong., 2d Sess. 11-13 (1974); S. Rep. No. 93-192, 93d Cong., 1st Sess. 21 (1973). This legislation indicates Congress' keen awareness of the problem of diversion and their willingness to consider sound proposals to meet the growing crisis. Again we can only re-emphasize that the merits of that portion of FDA's regulations under challenge here concern legislative issues which must first be addressed to Congress.

DUPLICATE
AFFIDAVIT OF SERVICE



Re: **74-1738**

**National Nutritional Foods Assoc. v.
Weinberger, et al**

**STATE OF NEW JERSEY :
: ss.:
COUNTY OF MIDDLESEX :**

I, **NATHANIEL LUTZ**, being duly sworn according to law,
and being over the age of 21 upon my oath depose and say
that: I am retained by the attorney for the above named
Plaintiffs-Appellants .

That on the 5th day of August , 19 74 I served the
within **Brief for Plaintiffs-Appellants** In the matter of
National Nutritional Foods v. Casper W. Weinberger, et al. ,
upon **Paul J. Curran, Esq., U.S. Attorney for Southern District** ,
U.S. Courthouse, Foley Square, New York, New York
by depositing two (2) true copies of the same securely
enclosed in a post-paid wrapper, in an official depository
maintained by the United States Government.

Nathaniel Lutz

Sworn to and subscribed
before me this 7th day
of August 1974.

**A Notary Public of the
State of New Jersey.**

LORRAINE LEOTTA
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires April 13, 1977.